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No. 85-1710

IN THE
Supreme Court of the United States
OCTOBER TERM, 1985

MALLINCKRODT, INC.,
Petitioner,

v.

SAMUEL F. BENNETT, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the Missouri Court of Appeals, Eastern District

MOTION FOR LEAVE TO FILE A BRIEF AS *AMICUS CURIAE* AND BRIEF OF THE AMERICAN COLLEGE OF NUCLEAR PHYSICIANS AS *AMICUS CURIAE* IN SUPPORT OF THE PETITION

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MOTION OF THE AMERICAN COLLEGE OF NUCLEAR PHYSICIANS FOR LEAVE TO FILE A BRIEF AS *AMICUS CURIAE* IN SUPPORT OF THE PETITION

The American College of Nuclear Physicians ("College") hereby requests, pursuant to Rule 36 of the Rules of this Court, leave to file the accompanying brief as *amicus curiae* in support of petitioner.* The *amicus* College is an organization of approximately 1200 physicians who specialize in research into and the practice of nuclear medicine. Nuclear medicine involves the use of ionizing and non-ionizing radiation by physicians in at-

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* Pursuant to Rule 36, *amicus* has obtained the written consent of the petitioner, but was denied consent to file by respondents. Petitioner's letter of consent has been filed with the Clerk of the Court.

tempting to diagnose various illnesses. See N. Alazraki & F. Mishkin, *Fundamentals of Nuclear Medicine* 3-15 (1984). Because the diagnostic techniques employ the use of radioactive materials, the College's members who employ these techniques do so under license issued to them or to the facilities where they practice by the Nuclear Regulatory Commission ("NRC") or its designate and they must comply with numerous stringent federal requirements for such uses of radioactive materials. See 10 C.F.R. parts 31 and 35 (1985). This case raises the basic issue of the extent to which compliance with NRC safety standards precludes a state tort suit based on alleged radiation injury. The *amicus* College believes that the Court, in deciding whether to grant the petition, would benefit from the views of the College whose members must operate under the potentially varying safety standards embodied in both the federal regulatory scheme and state tort law.

For the foregoing reasons, the *amicus* College's motion for leave to file a brief in support of petitioner should be granted.

Respectfully submitted,

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QUESTION PRESENTED

Amicus Curiae will address the following question:

Whether a state tort action is preempted by the Atomic Energy Act, 42 U.S. § 2011 *et seq.*, when the complaint, as construed by the state court, admits that the defendant operated in full compliance with all relevant safety standards established by the Nuclear Regulatory Commission.

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BRIEF OF THE AMERICAN COLLEGE OF NUCLEAR PHYSICIANS AS *AMICUS CURIAE* IN SUPPORT OF THE PETITION

INTEREST OF *AMICUS CURIAE*

The American College of Nuclear Physicians ("College") is a non-profit, Illinois corporation which was created in 1974 to foster the highest standards in nuclear medicine, to advance the science and practice of nuclear medicine and to promote the continuing competence of practitioners of nuclear medicine. The College has approximately 1200 members who practice nuclear medicine or conduct research in that discipline. Those members who handle nuclear materials do so pursuant to a license issued by the Nuclear Regulatory Commission or its designate and must comply with strict and extensive

federal regulations concerning the use of various radioactive materials in the diagnosis of illness. 10 C.F.R. parts 31 and 35 (1985).

In this case the petitioner, a producer of radiopharmaceuticals [1] which is licensed by the NRC, has been sued by a class of plaintiffs who allegedly have worked in the vicinity of one of petitioner's plants. The Missouri Court of Appeals has held that this tort action is not preempted by the Atomic Energy Act of 1954, 42 U.S.C. § 2011 *et seq.*, and its implementing regulations, even though under state law the complaint clearly fails to allege that petitioner violated any NRC regulation in causing respondents' alleged exposure to radiation.

This decision will directly and adversely affect the *amicus* College and its members in two ways. First, the decision will almost certainly drive most producers of radiopharmaceuticals away from this business. Very few companies will be prepared to risk exposure to billion dollar lawsuits which must be defended even if the manufacturer is in full compliance with a comprehensive federal regulatory scheme. What is even more likely is that no insurer will be willing to issue a liability insurance policy for conduct that can give rise to claims of such magnitude even though the conduct satisfies federal safety standards. See *Report of the Tort Policy Working Group on the Causes, Extent and Policy Implications of the Current Crisis in Insurance Availability*

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[1] Radiopharmaceuticals are made up of radioactive materials (a radionuclide) and a pharmaceutical which in combination allow for tailoring the chemical to permit tracing or therapy of a specific organ or other part of the body. *Fundamentals of Nuclear Medicine* at 12. Thus, petitioner's products can be developed to allow specialized imaging of the lungs, bone, liver, spleen, heart, brain and other vital parts. *Id.* at 13-14. Because of the special properties of radiopharmaceuticals for tracing bodily functions without disturbing their process they "provide a powerful diagnostic tool" for a host of serious disorders. *Id.* at 15.

and Affordability 6-15 (Feb. 1986) (documenting an existing insurance crisis). Thus, the effect of this decision will be to eliminate the supply of materials necessary for the practice of nuclear medicine, which in turn will jeopardize the health and lives of people whose illnesses can best be diagnosed by such techniques.

Second, assuming anyone is willing to continue producing radiopharmaceuticals, physicians who specialize in nuclear medicine, and who necessarily must expose people to radiation as part of their practice, will be seriously deterred both by the prospect of liability and the unavailability of insurance from continuing to practice nuclear medicine because of the potential for tort liability. This loss is unreasonable and unnecessary. The scientific evidence is overwhelming that the amount of radiation to which patients are exposed as part of this critical diagnostic function is *de minimis* compared to the level of radiation which occurs naturally. *Fundamentals of Nuclear Medicine* at 6; Upton, *The Biological Effects of Low-Level Ionizing Radiation*, 246 Scientific American 41, 42 (1982). Nevertheless, without a "safe harbor" based on compliance with NRC standards, the future of nuclear medicine seems quite bleak. The real victims, of course, will be those patients who will lose access to these diagnostic techniques which in many respects are superior to other methods, particularly because they do not require surgery.

Unless the decision below is reviewed by this Court, the practice of nuclear medicine will almost certainly end in Missouri and, because of the legal principles underlying the state court's decision, the practice of nuclear medicine in other states will just as certainly be altered significantly. Accordingly, the *amicus* College wishes to present its views to the Court on this important issue.

STATEMENT

A. The NRC's Regulation of Nuclear Medicine

The Atomic Energy Act directs the NRC "to exercise its powers in such manner as to insure the continued conduct of research and development and training activities in the . . . (3) utilization of special nuclear material and radioactive material for medical . . . purposes." 42 U.S.C. § 2051(a)(3). At the same time the NRC is instructed "to protect health [and] to minimize danger to life or property . . . ." § 2051(d). In addition, 42 U.S.C. § 2134(a) provides:

> The Commission is authorized to issue licenses to persons applying therefor for utilization facilities for use in medical therapy. In issuing such licenses the Commission is directed to permit the widest amount of effective medical therapy possible with the amount of special nuclear material available for such purposes and to impose the minimum amount of regulation consistent with its obligations under this chapter to promote the common defense and security and to protect the health and safety of the public.

Pursuant to this authorization, the NRC has adopted extensive regulations controlling the use and disposition of nuclear materials used by members of the *amicus* College who are regulated directly or indirectly by the Commission for receipt of such materials for their practice or research. 10 C.F.R. parts 31 and 35. The NRC's regulations place very precise limits upon the amount of various types of radioactive materials that a licensee can possess. 10 C.F.R. 31.11(a)(1)-(7). There are also very specific limitations on how certain materials can be administered to the patient. For instance, a licensee is prohibited from administering "to patients of technetium-99m containing more than 1 microcurie of molybdenum-99 per millicurie of technetium-99m, or more than 5 microcuries of molybdenum-99 per administered dose, at the

time of administration." 10 C.F.R. § 35.14(b)(4)(iii). Thus, where safety requires, the NRC can and does impose extremely specific requirements on licensees. The regulations for licensees such as petitioners are similarly detailed for the protection of public health and safety. 10 C.F.R. part 20.

B. Facts of the Case

Respondents represent a class of plaintiffs who have worked adjacent to petitioner's radiopharmaceutical processing plant in Maryland Heights, Missouri, Pet. App. 1a. Respondents claim that they have received physical and mental health injuries due to exposure to radioactive emissions released from petitioner's plant, and seek recovery under a number of common law tort theories. *Ibid.* Respondents have not alleged that petitioner, in exposing them to radiation, ever violated any NRC safety requirements. Respondents claim that the class is entitled to one billion dollars in damages.

The Circuit Court of St. Louis County summarily dismissed plaintiffs' claims, stating that the court lacked subject matter jurisdiction over the claims and that plaintiffs failed to state a cause of action. Pet. App. 30a.

The Missouri Court of Appeals reversed. Pet. App. 1a-26a. Although the court had misgivings about the state of the pleadings concerning the issue of petitioner's compliance with NRC regulations, the court of appeals expressly decided the case on the assumption that petitioner has complied with all relevant NRC standards because respondents never alleged any such violation. *Id.* at 6a-7a. The court then held that compliance with federal law did not create a basis for preempting a state common law tort action. It reasoned that it was not impossible for petitioner to comply with both federal and state standards for nuclear safety. Petitioner "can continue to meet federal standards, and, if found wanting by state standards, simply pay the piper." *Id.* at 5a. The court conceded that this result appeared to be "dis-

ingenuous and smacked of sophistry" (*ibid.*), but nevertheless held that it felt compelled to reach this result by this Court's recent decision in *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984).[2]

REASONS FOR GRANTING THE PETITION

The holding of the state court, permitting a billion dollar lawsuit to proceed without any allegation that petitioner has violated, even technically, any federal safety standards has sent shock waves through the nuclear medical community, whose members must expose individuals to radiation as part of their medical practice. It is critical that groups such as the *amicus* College and its members obtain a final ruling now on the preemption issue posed in the petition so that they can either realistically seek a clearer statement of preemption from Congress or abandon or modify the socially valuable practice of nuclear medicine. This case presents the Court with a unique and compelling opportunity to clarify its prior decision in *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984), and to establish clearly whether entities which fully comply with the requirements of the NRC enjoy any protection from state tort laws based on claims of exposure to radiation. Accordingly, the Court should grant the petition for a writ of certiorari.[3]

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[2] The Missouri Supreme Court denied petitioner's motion to transfer the case for review by that court. Pet. App. 29a.

[3] *Amicus* recognizes that this case is in an interlocutory posture, but that fact in this instance supports plenary review by this Court now rather than later. As we indicated previously, in the practice of nuclear medicine the amounts of radiation to which individuals are exposed, consistent with federal standards, are very small. Accordingly, the likelihood of there being any actual causal relationship between the radiation and alleged injuries is nil. Thus, defendants in these cases ordinarily should prevail, unless the fears of radiation arising from ignorance unduly influence the factfinder's determination. Thus, it is far from clear whether any final decision which poses the issue as clearly as this case does will come before the Court any time soon. In the interim, while the issue is

1. In *Silkwood* v. *Kerr-McGee Corp.* 464 U.S. 238 (1984), this Court considered whether punitive damages were an appropriate remedy in a state law tort action in which the company had violated NRC regulations and had failed to prevent the plaintiff from being exposed to plutonium. The Court reaffirmed its prior holding that "the federal government has occupied the entire field of nuclear safety concerns, except the limited powers ceded to the states." *Id.* at 249, quoting *Pacific Gas & Electric Co.* v. *State Energy Resources Conservation and Development Comm'n*, 461 U.S. 190, 212 (1983). At the same time, the Court held that Congress implicitly in the Atomic Energy Act and the Price-Anderson Act, 42 U.S.C. § 2210 *et seq.*, had generally ceded to the states the authority to apply their common law tort remedies at least in certain cases, including that one.

In describing its holding, the Court stated, "[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured *by illegal conduct.*" 464 U.S. at 251 (emphasis added). In so holding, the Court seemed to have used the violation of the NRC's rules, making the conduct illegal, as a predicate for its preemption analysis. Based on that premise, the Court held that imposition of punitive damages in that action would not "frustrate the objectives of the federal law." *Id.* at 256. In so doing the Court emphasized the apparent narrowness of its decision—"We perceive no such conflict or frustration in the circumstances *of this case.*" *Ibid.* (emphasis added) In addition, the Court expressly stated that "[w]e do not suggest that there could never be an instance in which

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litigated in the various states, the nuclear medical community will face potentially enormous litigation costs and potentially prohibitive insurance costs, even if insurance can be obtained at all. Because of the possibility of an aberrational result in tort litigation of the type represented by this case, as a practical matter, insurance coverage will disappear until the legal issue presented here is authoritatively decided by this Court.

the federal law would pre-empt the recovery of damages based on state law." *Ibid.*

The worthiness of this case for plenary review obviously depends in large measure on the intended scope of the Court's ruling in *Kerr-McGee.*[4] For several reasons *Kerr-McGee* should not apply to the situation posed in this case where no violation of federal law is alleged. First, the "disingenuousness" and "sophistry" of respondents' interpretation of *Kerr-McGee,* which so concerned the court of appeals, can be eliminated completely if state tort law is available only as a supplemental remedy for violations of federal safety standards. Even in that situation, the imposition of state tort liability will significantly affect how regulated entities handle nuclear materials and would likely cause most individuals to act well within federal limits to avoid the risk that a minor violation of federal law could give rise to significant tort liability, including punitive damages. But such an "interference" with federal regulation, which might otherwise warrant preemption,[5] clearly can be viewed as the "regulatory consequence . . . that Congress was willing to accept" which the Court identified in *Kerr-McGee.* 464 U.S. at 256.

Second, the Court stated in *Pacific Gas & Electric Co.* v. *Energy Resources Conservation and Development Comm'n,* 461 U.S. at 207, that "no role was left for the States" with respect to licensing for safety the "posses-

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[4] At a minimum, the court of appeals erred in applying only the most narrow preemption doctrine—whether federal and state law impose inconsistent obligations—and in failing completely to consider whether the state tort remedy, as applied, would interfere with the full achievement of Congress' purposes in the Atomic Energy Act. Compare *Florida Lime & Avocado Growers, Inc.* v. *Paul,* 373 U.S. 132, 142-143 (1963) with *Hines* v. *Davidowitz,* 312 U.S. 52, 67 (1941). See *Fidelity Federal Savings & Loan Ass'n* v. *De La Cuesta,* 458 U.S. 141, 153 (1982).

[5] Compare *Ray* v. *Atlantic Richfield Co.,* 435 U.S. 151 (1978); *San Diego Building Trades Council* v. *Garmon,* 359 U.S. 236 (1959).

sion and use of nuclear material." The decision of the court of appeals has rendered this statement a nullity. Instead of federal preemption of the nuclear safety field, there is virtually no role left for the federal government.

With enormous liability and litigation costs as the ultimate sanction for all radioactive exposure, even that authorized by the NRC, federal safety standards will become irrelevant. Whatever ad hoc standards a judge or jury sets will become the only meaningful requirements. Of course, no users of nuclear materials, who, like members of the *amicus* College, must expose individuals to radiation can possibly know in advance what conduct on their part will be found actionable by a trier of fact. Thus, in place of the NRC's detailed requirements for the safe use of nuclear materials regulating the practice of nuclear medicine, the decision below will substitute an essentially standardless state tort system. The reasonableness of the physicians' actions will be judged by lay juries ill-equipped to make such judgments in an area as complex as radiation safety. Neither the Congress in the Atomic Energy Act nor the Court in *Kerr McGee* could have intended this result.

This conclusion is reinforced by the fact that in other areas where a federal agency has been delegated broad regulatory authority, this Court has held that compliance with federal standards precludes state damage actions. See *Chicago & N.W. Transportation Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 326-327 (1981); *Pennsylvania R. Co.* v. *Clark Bros. Coal Mining Co.*, 238 U.S. 456, 469 (1915) (damages precluded absent a finding by ICC of illegality). Against this background it is reasonable to assume that the violation of the NRC's regulations was critical to the Court's ultimate holding in *Kerr-McGee.*

2. The court of appeals' reading of *Kerr-McGee* conflicts with the interpretations of this Court's decision by other state courts and jurists. For instance, in *Elsworth* v. *Beech Aircraft Corp.*, 37 Cal. 3d 540, 208 Cal. Reptr.

874, 691 P.2d 630, 635 (1984) (emphasis added), the California Supreme Court, in an opinion by Justice Mosk, argued that *Silkwood* stood for "the proposition that even if the federal government has entirely occupied the field of regulating an activity *a state may simultaneously grant damages for violation of such regulation.*" Similarly, in *Nappe* v. *Anschelewitz, Barr, Ansell & Bonello*, 97 N.J. 37, 477 A.2d 1224, 1237 (1984), a concurring justice reasoned that in *Silkwood* this Court "held that punitive damages under state law could be recovered for violation of nuclear energy regulations . . . ." Cf. *Cipollone* v. *Liggett Group, Inc.*, No. 85-5073 (3d Cir. Apr. 7, 1986) (claims for failure adequately to warn about cigarette smoking preempted by Federal Cigarette Labeling and Advertising Act).

These cases illustrate that the scope of *Kerr-McGee* is completely unsettled in the lower courts. In light of the legitimate uncertainty surrounding the proper interpretation of *Kerr-McGee* and given that the issue literally will determine the future of socially valuable practices, such as nuclear medicine, the Court should grant the petition and decide whether this is the "instance in which federal law would preempt the recovery of damages based on state law" which the Court anticipated in *Kerr-McGee*.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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